Paclitaxel Albumin-Bound:
Abraxane®; Paclitaxel Albumin-Bound Ψ
(Intravenous)

Document Number: IC-0001

Last Review Date: 12/03/2024
Date of Origin: 10/17/2008
Dates Reviewed: 06/2009, 12/2009, 07/2010, 09/2010, 12/2010, 03/2011, 06/2011, 09/2011, 12/2011, 03/2012, 06/2012, 09/2012, 11/2012, 12/2012, 03/2013, 06/2013, 09/2013, 12/2013, 03/2014, 06/2014, 09/2014, 12/2014, 03/2015, 05/2015, 08/2015, 11/2015, 02/2016, 05/2016, 08/2016, 11/2016, 02/2017, 05/2017, 08/2017, 11/2017, 02/2018, 04/2018, 05/2018, 09/2018, 12/2018, 03/2019, 06/2019, 09/2019, 12/2019, 03/2020, 06/2020, 09/2020, 12/2020, 03/2021, 06/2021, 09/2021, 12/2021, 03/2022, 06/2022, 09/2022, 12/2022, 03/2023, 06/2023, 09/2023, 12/2023, 03/2024, 06/2024, 09/2024, 12/2024

I. Length of Authorization

Coverage is provided for 6 months and may be renewed, unless otherwise specified.

- Non-Small Cell Lung Cancer (NSCLC) in combination with tremelimumab, durvalumab, and carboplatin OR in combination with pembrolizumab and carboplatin: Coverage will be provided for up to a maximum of 12 weeks of therapy (12 doses) and may NOT be renewed.
- Non-Small Cell Lung Cancer (NSCLC) in combination with atezolizumab and carboplatin: Coverage will be provided for up to a maximum of 18 weeks of therapy (18 doses) and may NOT be renewed.
- Neoadjuvant therapy for Ampullary Adenocarcinoma: Coverage will be provided for up to a maximum of 24 weeks of therapy (18 doses) and may NOT be renewed.
- Neoadjuvant therapy for Gallbladder Cancer: Coverage will be provided for up to a maximum of 24 weeks of therapy (18 doses) and may NOT be renewed.
- Neoadjuvant and induction therapy in combination with gemcitabine for Pancreatic Adenocarcinoma: Coverage will be provided for up to a maximum of 24 weeks of therapy (18 doses) and may NOT be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

Kaposi Sarcoma
- 300 billable units per 28 days

NSCLC
- 900 billable units per 21 days

Cervical Cancer, Biliary Tract Cancers, Vaginal Cancer, & Ampullary Adenocarcinoma
- 900 billable units per 28 days

Breast Cancer, Small Bowel Adenocarcinoma, Pancreatic Adenocarcinoma, Ovarian Cancer, Fallopian Tube & Primary Peritoneal Cancer, Endometrial Carcinoma

- 2800 billable units per 84 days

Cutaneous & Uveal Melanoma

- 1200 billable units per 28 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Breast Cancer † ‡ [1-3,9,21,27]

- Patient failed on combination chemotherapy for metastatic disease or relapsed within 6 months of adjuvant therapy †; **AND**
  - Used as a single agent; **AND**
  - Previous chemotherapy included an anthracycline unless clinically contraindicated; **OR**
- Patient has recurrent unresectable (local or regional) or metastatic (stage IV [M1]) disease OR inflammatory breast cancer with no response to preoperative systemic therapy ‡; **AND**
  - Patient has HER2-negative hormone receptor-positive disease; **AND**
    - Patient is refractory to endocrine therapy or has visceral crisis; **AND**
    - Used as one of the following:
      - As a single agent
      - In combination with carboplatin in patients with high tumor burden, rapidly progressing disease, or visceral crisis; **AND**
    - Used in one of the following treatment settings:
      - First-line therapy if no germline BRCA 1/2 mutation
      - Second-line therapy if not a candidate for fam-trastuzumab deruxtecan-nxki
      - Third-line therapy and beyond; **OR**
  - Patient has triple negative breast cancer (TNBC) ***; **AND**
    - Used in combination with pembrolizumab for PD-L1 positive (PD-L1 CPS ≥10) disease; **OR**
    - Used as a single agent; **AND**
      - Used as first-line therapy if PD-L1 CPS <10 and no germline BRCA 1/2 mutation; **OR**
      - Used as subsequent therapy; **OR**
    - Used in combination with carboplatin in patients with high tumor burden, rapidly progressing disease, or visceral crisis; **AND**
      - Used as first-line therapy if PD-L1 CPS <10 and no germline BRCA 1/2 mutation; **OR**
      - Used as subsequent therapy; **OR**

- Patient has HER2-positive disease; **AND**
  - Used as fourth-line therapy and beyond in combination with trastuzumab; **OR**
- May be substituted for paclitaxel or docetaxel if the patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedication ‡

Non-Small Cell Lung Cancer (NSCLC) † ‡ [1,2,4,10,30-32]

- Used as first-line therapy for locally advanced or metastatic disease, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy †; **OR**
- May be substituted for paclitaxel or docetaxel if the patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedication; **OR**
- Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first-line therapy; **AND**
    - Used in one of the following:
      - Patients with a performance status (PS) 0-1 who have tumors that are negative for actionable molecular biomarkers***** (may be KRAS G12C mutation positive) and PD-L1 <1%
      - Patients with tumors that are negative for actionable molecular biomarkers***** (may be KRAS G12C mutation positive) and PD-L1 expression positive (≥1%)
      - Patients with a PS 0-1 who have tumors that are positive for one of the following molecular mutations: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, RET rearrangement, or ERBB2 (HER2); **AND**
      - Used in combination with carboplatin and pembrolizumab for squamous cell histology; **OR**
      - Used in combination with carboplatin and atezolizumab for non-squamous histology; **OR**
      - Used in combination with tremelimumab, durvalumab, and carboplatin *(excluding use in patients with PD-L1 ≥50%)*; **OR**
    - Used as a single agent (PS 2) or in combination with carboplatin in patients with contraindications **¥** to PD-1 or PD-L1 inhibitors; **AND**
      - Used in patients with tumors that are negative for actionable molecular biomarkers***** (may be KRAS G12C mutation positive); **OR**
      - Used in patients with tumors that are positive for one of the following molecular mutations: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); **OR**
  - Used as subsequent therapy; **AND**
    - Used in one of the following:

- Patients with a PS 0-1 who are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, or RET rearrangement
- Patients with a PS 0-1 who are positive for one of the following molecular mutations and have received prior targeted therapy**§** for those aberrations: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; **AND**

– Used in combination with carboplatin and pembrolizumab for squamous cell histology; **OR**

– Used in combination with carboplatin and atezolizumab for non-squamous histology; **OR**

– Used in combination with tremelimumab, durvalumab, and carboplatin; **OR**

- Used in combination with carboplatin in patients with contraindications **¥** to PD-1 or PD-L1 inhibitors; **AND**
  - Used in patients with tumors that are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; **OR**
  - Used in patients with tumors that are positive for one of the following molecular mutations and have received prior targeted therapy**§** for those aberrations: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; **OR**
  - Used in patients with PD-L1 expression-positive (≥1%) tumors that are negative for actionable molecular biomarkers***** with prior PD-1/PD-L1 inhibitor therapy but no prior platinum-containing chemotherapy; **OR**
- Used as a single agent; **AND**
  - Used for first progression after initial systemic therapy (if not previously used); **OR**
  - Used in patients with a PS 2 who are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; **OR**
  - Used in patients with a PS 2 who are positive for one of the following molecular mutations and have received prior targeted therapy**§** for those aberrations: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; **OR**
  - Used in patients with a PS 2 and PD-L1 expression-positive (≥1%) tumors that are negative for actionable molecular biomarkers***** with prior PD-1/PD-L1 inhibitor therapy but no prior platinum-containing chemotherapy

***Note:** Actionable molecular genomic biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2). Complete genotyping for EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2), via biopsy and/or plasma testing. If a clinically actionable marker is found, it is reasonable to*

start therapy based on the identified marker. Treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.
¥ Note: Contraindications for treatment with PD-1/PD-L1 inhibitors may include active or previously documented autoimmune disease and/or current use of immunosuppressive agents, and some oncogenic drivers (e.g., EGFR exon 19 deletion or exon 21 L858R, ALK rearrangements) have been shown to be associated with less benefit from PD-1/PD-L1 inhibitors.

Ovarian, Fallopian Tube, and Primary Peritoneal Cancer ‡ [2,8,22]

- Patient has Grade 1 Endometrioid Carcinoma, Carcinosarcoma (Malignant Mixed Müllerian Tumors), Mucinous Neoplasms of the Ovary, Epithelial Ovarian/Fallopian Tube/Primary Peritoneal Cancer, Clear Cell Carcinoma of the Ovary; **AND**
  - Patient has recurrent or persistent disease; **AND**
  - Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); **AND**
    - Used as one of the following:
      - As a single agent
      - In combination with carboplatin in patients with confirmed taxane hypersensitivity; **AND**
    - Patient has one of the following:
      - Platinum-resistant disease; **AND**
        - Used for progression on primary, maintenance, or recurrence therapy; **OR**
        - Used for stable or persistent disease if not currently on maintenance therapy; **OR**
        - Used for complete remission and relapse <6 months after completing chemotherapy; **OR**
      - Platinum-sensitive disease; **AND**
        - Used for complete remission and relapse ≥6 months after completing chemotherapy; **OR**
- Patient has low-grade serous carcinoma; **AND**
  - Patient has recurrent disease; **AND**
    - Used as a single agent; **OR**
    - Used in combination with carboplatin in patients with confirmed taxane hypersensitivity; **OR**
- May be substituted for paclitaxel if the patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedication

Pancreatic Adenocarcinoma † ‡ Φ [1,2,5-7,24,34,35]

- Used in combination with gemcitabine; **AND**

- Patient has locally advanced or metastatic disease; **AND**
  - Used as first-line therapy; **OR**
  - Used as induction therapy followed by chemoradiation *(locally advanced disease only)*; **OR**
  - Used as subsequent therapy after disease progression with a fluoropyrimidine-based therapy; **OR**
- Patient has local recurrence in the pancreatic operative bed OR recurrent metastatic disease after resection; **AND**
  - Used ≥6 months after completion of primary therapy; **OR**
  - Used <6 months from completion of primary therapy and previously treated with fluoropyrimidine-based therapy; **OR**
- Used as neoadjuvant therapy; **AND**
  - Patient has resectable disease; **OR**
  - Patient has biopsy positive borderline resectable disease; **OR**

- Used in combination with gemcitabine and cisplatin; **AND**
  - Patient has metastatic disease; **AND**
  - Patient has ECOG PS 0-1; **AND**
  - Used as first-line therapy

Cutaneous Melanoma ‡ [2,15,16]

- Patient has metastatic or unresectable disease; **AND**
- Used as subsequent therapy as a single agent or in combination with carboplatin; **AND**
- Used for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc.)

Uveal Melanoma ‡ [2,15,16]

- Used as a single agent for metastatic or unresectable disease

Endometrial Carcinoma (Uterine Neoplasms) ‡ [2,20]

- Used as single agent therapy; **AND**
- Used as subsequent therapy for recurrent disease; **AND**
- Patient has tried paclitaxel and treatment with paclitaxel was not tolerated due to a documented hypersensitivity reaction, despite use of recommended premedication or there is a documented medical contraindication to recommended premedication; **AND**
- Patient has a negative skin test to paclitaxel (if available)

Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma) ‡ [2,11,35]

- Used in combination with gemcitabine; **AND**
  - Patient has unresectable, resected gross residual (R2), or metastatic disease; **AND**

        - Used as primary treatment; **OR**
        - Use as subsequent treatment for progression on or after systemic therapy; **OR**
    - Patient has resectable locoregionally advanced gallbladder cancer; **AND**
        - Used as neoadjuvant therapy; **AND**
            - Patient has incidental finding of suspicious mass during surgery where hepatobiliary surgery expertise unavailable; **OR**
            - Patient has incidental finding on pathologic review (cystic duct node positive); **OR**
            - Patient has mass on imaging

Small Bowel Adenocarcinoma ‡ [2,17,18,26]

- Patient has advanced or metastatic disease; **AND**
- Used as single agent or in combination with gemcitabine; **AND**
    - Used as initial therapy after previous FOLFOX/CAPEOX in the adjuvant setting within past 12 months or contraindication; **OR**
    - Used as subsequent therapy if not previously given

Kaposi Sarcoma ‡ [2,19,25]

- Used as subsequent therapy in patients intolerant to paclitaxel; **AND**
- Patient has relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease; **AND**
- Disease has progressed on or not responded to first-line systemic therapy; **AND**
- Disease has progressed on alternate first-line systemic therapy; **AND**
    - Used as a single agent for patients that do not have HIV; **OR**
    - Used in combination with antiretroviral therapy (ART) for patients with HIV

Ampullary Adenocarcinoma ‡ [2,24]

- Used in combination with gemcitabine; **AND**
- Patient has pancreatobiliary or mixed type disease; **AND**
    - Used as neoadjuvant therapy for localized disease in high-risk patients (i.e., equivocal or indeterminate imaging findings, markedly elevated CA 19-9, markedly elevated carcinoembryonic antigen [CEA], large primary tumors, large regional lymph nodes, excessive weight loss, extreme pain); **OR**
    - Used as first-line therapy for unresectable localized or metastatic disease; **OR**
    - Used as subsequent therapy for disease progression

Cervical Cancer ‡ [2,28]

- Used as a single agent as subsequent therapy; **AND**
    - Patient has persistent, recurrent, or metastatic small cell neuroendocrine carcinoma of the cervix (NECC); **OR**
    - Patient has recurrent or metastatic disease

Vaginal Cancer ‡ [2]

- Used as a single agent as subsequent therapy; **AND**
- Patient has recurrent or metastatic disease

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); **Φ** Orphan Drug

***** ER Scoring Interpretation** *(following ER testing by validated IHC assay)[21]*	
Results	**Interpretation**
– 0% – <1% of nuclei stain	– ER-negative
– 1%–10% of nuclei stain	– ER-low–positive*
– >10% of nuclei stain	– ER-positive
**Note: Invasive cancers with between 1%–10% ER positivity are considered ER-low–positive. However, this group is noted to be heterogeneous and the biologic behavior of ER-low–positive cancers may be more similar to ER-negative cancers. This should be considered in decision making for other adjuvant therapy and overall treatment pathway.*	

§Genomic Aberration/Mutational Driver Targeted Therapies (Note: *not all inclusive, refer to guidelines for appropriate use*)			
EGFR exon 19 deletion or exon 21 L858R tumors	*EGFR* S768I, L861Q, and/or G719X mutation positive tumors	*EGFR* exon 20 insertion mutation positive tumors	*NTRK1/2/3* gene fusion positive tumors
– Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib – Amivantamab	– Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib – Amivantamab	– Amivantamab	– Larotrectinib – Entrectinib – Repotrectinib
ALK rearrangement-positive tumors	*ROS1* rearrangement-positive tumors	*BRAF* V600E-mutation positive tumors	*ERBB2 (HER2)* mutation positive tumors
– Alectinib – Brigatinib – Ceritinib – Crizotinib – Lorlatinib	– Ceritinib – Crizotinib – Entrectinib – Lorlatinib – Repotrectinib	– Dabrafenib ± trametinib – Encorafenib + binimetinib – Vemurafenib	– Fam-trastuzumab deruxtecan-nxki – Ado-trastuzumab emtansine
PD-L1 tumor expression ≥ 1%	*MET* exon-14 skipping mutations	*RET* rearrangement-positive tumors	*KRAS G12C* mutation positive tumors
– Pembrolizumab – Atezolizumab – Nivolumab + ipilimumab – Cemiplimab – Tremelimumab + durvalumab	– Capmatinib – Crizotinib – Tepotinib	– Selpercatinib – Cabozantinib – Pralsetinib	– Sotorasib – Adagrasib

IV. Renewal Criteria [1,2]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**

- Duration of authorization has not been exceeded *(refer to Section I)*; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe myelosuppression (e.g., severe neutropenia [absolute neutrophil count < 1,500 cell/mm^3] or thrombocytopenia), sensory neuropathy, sepsis, pneumonitis, severe hypersensitivity reactions (including anaphylactic reactions), hepatic impairment, etc.

V. Dosage/Administration [1,11,15,16-19,21,22,25-46]

Indication	Dose
Breast Cancer	<u>Single agent:</u> Administer 260 mg/m² intravenously every 21 days until disease progression or unacceptable toxicity OR Administer 100 mg/m² OR 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity <u>In combination with pembrolizumab:</u> Administer 100 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity <u>In combination with carboplatin:</u> Administer 125 mg/m² intravenously days 1 and 8 of a 21-day cycle until disease progression or unacceptable toxicity <u>In combination with trastuzumab:</u> Administer 260 mg/m² intravenously day 1 of a 21-day cycle until disease progression or unacceptable toxicity OR Administer 100 mg/m² OR 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity ***Note:** If being used as a substitute for weekly paclitaxel or docetaxel, the weekly dose of albumin-bound paclitaxel should not exceed 125 mg/m²*
NSCLC	<u>Single agent:</u> Administer 260 mg/m² intravenously every 21 days until disease progression or unacceptable toxicity OR Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity <u>In combination with carboplatin:</u>

	Administer 100 mg/m² intravenously days 1, 8, and 15 of a 21-day cycle until disease progression or unacceptable toxicity In combination with tremelimumab, durvalumab, and carboplatin: Administer 100 mg/m² intravenously days 1, 8, and 15 of a 21-day cycle for 4 cycles In combination with pembrolizumab and carboplatin: Administer 100 mg/m² intravenously days 1, 8, and 15 of a 21-day cycle for 4 cycles In combination with atezolizumab and carboplatin: Administer 100 mg/m² intravenously days 1, 8, and 15 of a 21-day cycle for 4 to 6 cycles
Ovarian Cancer, Fallopian Tube Cancer, & Primary Peritoneal Cancer	Single agent: Administer 260 mg/m² intravenously day 1 of a 21-day cycle until disease progression or unacceptable toxicity All other treatment settings: Administer 100 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity
Kaposi Sarcoma	Administer 100 mg (fixed dose) intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity
Cutaneous Melanoma	Single agent: Administer 100 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity OR Administer 150 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity In combination with carboplatin: Administer 100 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity
Uveal Melanoma	Administer 100 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity OR Administer 150 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity
Endometrial Carcinoma	Administer 260 mg/m² intravenously on day 1 of a 21- day cycle until disease progression or unacceptable toxicity OR Administer 100 - 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity

Cervical Cancer, Vaginal Cancer	Administer 100 - 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity
Ampullary Adenocarcinoma, Biliary Tract Cancers	Neoadjuvant therapy for gallbladder cancer: Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle for 6 cycles All other treatment settings: Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity
Pancreatic Adenocarcinoma	In combination with gemcitabine for neoadjuvant therapy: Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle for 6 cycles In combination with gemcitabine as induction therapy: Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity for 4 - 6 cycles In combination with gemcitabine for all other settings: Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity In combination with gemcitabine and cisplatin: Administer 100 - 125 mg/m² intravenously days 1 and 8 of a 21-day cycle until disease progression or unacceptable toxicity
Small Bowel Adenocarcinoma	Single agent: Administer 220 – 260 mg/m² intravenously every 21 days until disease progression or unacceptable toxicity In combination with gemcitabine: Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity

VI. Billing Code/Availability Information

HCPCS Code(s):

- J9264 – Injection, paclitaxel protein-bound particles, 1 mg; 1 billable unit = 1 mg
- J9259 – Injection, paclitaxel protein-bound particles (american regent), not therapeutically equivalent to J9264, 1 mg; 1 billable unit = 1 mg **Ψ** *(Discontinue use on 01/01/2025)*

NDC:

- Abraxane 100 mg powder for injection; single-dose vial*****: 68817-0134-xx

Multiple manufacturers produce ANDA generics
Ψ *Designated products approved by the FDA as a 505(b)(2) NDA of the innovator product. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration's (FDA) Orange Book and are therefore considered single source products based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Act. For a complete list of all approved 505(b)(2) NDA products please reference the latest edition of the Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book | FDA*

VII. References

1. Abraxane [package insert]. Princeton, NJ; Bristol-Myers Squibb Company; October 2022. Accessed November 2024.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) paclitaxel, albumin bound. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed November 2024.
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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.3	Meckel's diverticulum, malignant
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
C22.1	Intrahepatic bile duct carcinoma
C23	Malignant neoplasm of the gallbladder
C24.0	Malignant neoplasm of extrahepatic bile duct
C24.1	Malignant neoplasm of ampulla of Vater

ICD-10	ICD-10 Description
C24.8	Malignant neoplasm of overlapping sites of biliary tract
C24.9	Malignant neoplasm of biliary tract, unspecified
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of the pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus or lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C43.0	Malignant melanoma of lip
C43.111	Malignant melanoma of right upper eyelid, including canthus
C43.112	Malignant melanoma of right lower eyelid, including canthus
C43.121	Malignant melanoma of left upper eyelid, including canthus
C43.122	Malignant melanoma of left lower eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant neoplasm of right ear and external auricular canal
C43.22	Malignant neoplasm of left ear and external auricular canal
C43.30	Malignant melanoma of unspecified parts of face

ICD-10	ICD-10 Description
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
C46.0	Kaposi's sarcoma of skin
C46.1	Kaposi's sarcoma of soft tissue
C46.2	Kaposi's sarcoma of palate
C46.3	Kaposi's sarcoma of lymph nodes
C46.4	Kaposi's sarcoma of gastrointestinal sites
C46.50	Kaposi's sarcoma of unspecified lung
C46.51	Kaposi's sarcoma of right lung
C46.52	Kaposi's sarcoma of left lung
C46.7	Kaposi's sarcoma of other sites
C46.9	Kaposi's sarcoma, unspecified
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast

ICD-10	ICD-10 Description
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast

ICD-10	ICD-10 Description
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C52	Malignant neoplasm of vagina
C53.0	Malignant neoplasm of endocervix
C53.1	Malignant neoplasm of exocervix
C53.8	Malignant neoplasm of overlapping sites of cervix uteri
C53.9	Malignant neoplasm of cervix uteri, unspecified
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part unspecified
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament

ICD-10	ICD-10 Description
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified
C69.30	Malignant neoplasm of unspecified choroid
C69.31	Malignant neoplasm of right choroid
C69.32	Malignant neoplasm of left choroid
C69.40	Malignant neoplasm of unspecified ciliary body
C69.41	Malignant neoplasm of right ciliary body
C69.42	Malignant neoplasm of left ciliary body
C69.60	Malignant neoplasm of unspecified orbit
C69.61	Malignant neoplasm of right orbit
C69.62	Malignant neoplasm of left orbit
Z85.068	Personal history of other malignant neoplasm of small intestine
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.09	Personal history of malignant neoplasm of other digestive organs
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.3	Personal history of malignant neoplasm of breast
Z85.42	Personal history of malignant neoplasm of other parts of uterus
Z85.43	Personal history of malignant neoplasm of ovary

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	**NCD/LCA/LCD Document (s)**	**Contractor**
6, K	A52450	National Government Services, Inc. (NGS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC